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600-1-285N

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Kreek, M.J. et al.
SERIAL NO. : 09/904,584 EXAMINER : Lockard, J.M.
FILED : July 13, 2001 ART UNIT : 1647
FOR : ALLELES OF THE HUMAN KAPPA OPIOID RECEPTOR GENE,
DIAGNOSTIC METHODS USING SAID ALLELES, AND
METHODS OF TREATMENT BASED THEREON

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

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Anne M. Jones

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RESPONSE TO RESTRICTION REQUIREMENT

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

Dear Sir:

The following reply is responsive to the Requirement for Restriction mailed June 21, 2004, due for a response on July 21, 2004.

In the Requirement for Restriction, the Examiner requested election of one of the following groups:

- Group I: Claims 30-46 and 58-59, drawn to nucleic acids, vector, host cells, and detection of nucleic acids using PCR.
- Group II: Claims 47-57, drawn to methods of determining susceptibility in a subject to a physiological response and determining a therapeutically effective

amount of agent to administer to an individual in response to said physiological response via screening for alleles of the human kappa oloid receptor gene.

Furthermore, the Examiner notes that in addition to the above restriction requirement, a further election of species is required. In particular, if Applicants elect the invention of Group I, an election of one of the specific promoters recited in claim 43 is required. If Applicants elect the invention of Group II, an election of one of the specific conditions or diseases in claim 47 is required.

Applicants hereby elect Group I, claims 30-46 and 58-59, drawn to nucleic acids, vector, host cells, and detection of nucleic acids using PCR, with traverse. With respect to the species election, Applicants hereby elect the immediate early promoters of hCMV.

Applicants respectfully request reconsideration of the Requirement for Restriction, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully assert that the search for the nucleic acids of Group I claims would result in a search of related subject matter for the methods of Group II claims. In particular, several of the claims from Group II depend from, or recite the nucleic acid sequence identifier of Group I claims, such as claim numbers 47, 50, 51, 53, 54, 55, 56, 57,

58 and 59. Accordingly, Applicants assert that a search on the nucleic acids of Group I claims as elected, would require a search on related, if not, identical subject matter.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,



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